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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,817	01/18/2002	Eduard N. Lerner	10087 P04CIP1	9018
23117	7590	04/15/2004	EXAMINER	
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714			AZPURU, CARLOS A	
		ART UNIT	PAPER NUMBER	
		1615		

DATE MAILED: 04/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/051,817	LERNER, EDUARD N.
<b>Examiner</b>	<b>Art Unit</b>	
Carlos A. Azpuru	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on \_\_\_\_.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-31 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-6,8,11,12,16 and 21-31 is/are rejected.

7)  Claim(s) 7,9,13-15 and 17-20 is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152

Priority under 35 U.S.C. § 119

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a))

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_

## **DETAILED ACTION**

Receipt is acknowledged of the request for reconsideration filed 02/02/2004.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-31 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in that the spinal cord and intrabrain zones are already within the CNS, and not adjacent to the CNS as set out in the claimed method. This would appear to contradict the claimed method. Clarification is requested.

Claims 2-5 are indefinite in that they do not point out what each of the various anatomical areas "is used" for in the claimed method. Also it is the use of the term "ocular (optic nerve) system" appears to be contradictory to the claimed method because the optic nerve is located within the central nervous system. Clarification is requested.

Claim 16 is indefinite in that the metes and bounds of the Markush Group are not particularly set out by the term metal salts (e.g. silver chloride). Clarification and correction are requested.

***Double Patenting***

Claims 1-6, 8,11, 12, 21-30, and 31 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-12 of copending Application No. 10/050183 ('183). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

US Patent application '183 claims a method and apparatus for delivery of a biologically active agent into the CNS bypassing the blood-brain barrier by setting up an energy gradient from an external point to the epidural space (brain surface). The energy gradient may be either iontophoretic or phonophoretic. The instant claims are directed to the same invention.

Claims 1-6, 8, 11, 12, 21-30, and 31 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-12 of copending Application No. 10/687,816 ('816). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

US Patent application '816 claims a method and apparatus for delivery of a biologically active agent into the CNS bypassing the blood-brain barrier by setting up an

energy gradient from an external point to the epidural space (brain surface). The energy gradient may be either iontophoretic or phonophoretic. The instant claims are directed to the same invention.

Claims 7, 9, 13-15, 17-19 are objected to as dependent upon a rejected base claim.

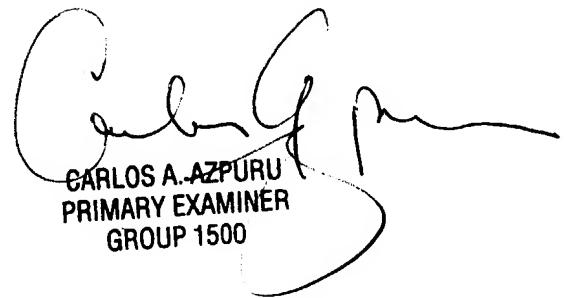
US Patent 6,410,046 is cited as a patent of interest in its disclosure of using an energy gradient to transport bioactives to the CNS. The method of '046 requires a permeation enhancer not found in the instant application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0602. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0588. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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